

1 MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

2
3 CERTIFICATE OF NEED (CON) REVIEW STANDARDS
4 FOR BONE MARROW TRANSPLANTATION SERVICES
5

6 (By authority conferred on the Certificate of Need CON Commission by Section 22215 of Act No. 368 of
7 the Public Acts of 1978, as amended, and Sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as
8 amended, being Sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)
9

10 **Section 1. Applicability**

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12 Sec. 1. (1) These standards are requirements for the approval and delivery of services for all
13 projects approved and Certificates of Need issued under Part 222 of the Code which involve bone marrow
14 transplantation services.
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16 (2) A bone marrow transplantation service is a covered clinical service for purposes of Part 222 of
17 the Code.
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19 (3) A bone marrow transplantation service listed on the Department inventory that is not located at
20 a licensed hospital site and that performs only autologous bone marrow transplantation procedures using
21 stem cells obtained from the peripheral circulation shall be required to obtain Certificate of Need CON
22 approval to provide a bone marrow transplantation service that performs allogeneic bone marrow
23 transplantation procedures or bone marrow transplantation procedures that use stem cells obtained from
24 any other source other than the peripheral circulation. A bone marrow transplantation service listed on the
25 Department inventory that is located at a hospital site and initially does not perform both allogeneic and
26 autologous procedures shall not be required to obtain separate Certificate of Need CON approval to begin
27 performing both autologous and allogeneic bone marrow transplant procedures.
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29 (4) An existing bone marrow transplantation service that performs only adult procedures shall
30 require separate Certificate of Need CON approval in order to perform pediatric procedures. An existing
31 bone marrow transplantation service that performs only pediatric procedures shall require separate
32 Certificate of Need CON approval in order to perform adult procedures.
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34 (5) The Department shall use Section 3, as applicable, in applying Section 22225(1) of the Code,
35 being Section 333.22225(1) of the Michigan Compiled Laws.
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37 (6) The Department shall use Section 56, as applicable, in applying Section 22225(2)(c) of the
38 Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.
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40 **Section 2. Definitions**

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42 Sec. 2. (1) As used in these standards:

43 (a) "Adult," for purposes of these standards, means an individual age 18 or older.

44 (b) "Allogeneic" means transplantation between genetically nonidentical individuals of the same
45 species.

46 (c) "Autologous" means transplantation in which the donor and recipient are the same individual.

47 (d) "Bone marrow transplantation service" means the transplantation of proliferating hematopoietic
48 stem cells essential to the survival of a patient derived from the bone marrow, the peripheral circulation,
49 cord blood, or any other source.

50 (e) "Certificate of Need Commission" or "CON Commission" means the Commission created
51 pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

52 (f) "Comparative group" means the applications that have been grouped for the same type of
53

project in the same planning area and are being reviewed comparatively in accordance with the [Certificate of NeedCON](#) rules.

(g) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(h) "Department" means ~~the state agency known as~~ the Michigan Department of Community Health (MDCH).

(i) "Department inventory of bone marrow transplantation services" means the list set forth in Appendix A and maintained by the Department of: (i) the bone marrow transplantation services operating pursuant to a valid [Certificate of NeedCON](#) issued under Part 222 or former Part 221; (ii) operating bone marrow transplantation services for which the operation of that service did not require a [Certificate of NeedCON](#); and (iii) bone marrow transplantation services that are not yet operational but have a valid [Certificate of NeedCON](#) issued under Part 222. The list shall inventory adult and pediatric services separately and shall specify the site at which the bone marrow transplantation service is authorized.

(j) "Existing bone marrow transplantation service," for purposes of Section 3(5) of these standards, means any of the following: (i) a bone marrow transplantation service listed on the Department inventory, (ii) a proposed bone marrow transplantation service under appeal from a final decision of the Department, or (iii) a proposed bone marrow transplantation service that is part of a completed application under Part 222 (other than the application under review) for which a proposed decision has been issued and which is pending final decision.

(k) "Health service area" or "HSA" means the geographic area set forth in Section 78.

(l) "Implementation plan" means a plan that documents how a proposed bone marrow transplantation service will be initiated within the time period specified in these standards or the [Certificate of NeedCON](#) rules. At a minimum, the implementation plan shall identify:

(i) each component or activity necessary to begin performing the proposed bone marrow transplantation service including, but not limited to, the development of physical plant requirements, such as an intensive care unit capable of treating immuno-suppressed patients, equipment acquisitions, and recruitment and employment of all physician and support staff;

(ii) the time table for completing each component or activity specified in subsection (i); and

(iii) if the applicant previously has been approved for a bone marrow transplantation service for which either the [Certificate of NeedCON](#) expired or the service did not perform a transplant procedure during any consecutive 12-month period, what changes have or will be made to ensure that the proposed service can be initiated and provided on a regular basis.

(m) "Initiate" or "implement" for purposes of these standards, means the performance of the first transplant procedure. The term of an approved [Certificate of NeedCON](#) shall be 18 months or the extended period established by Rule 325.9403(2), if authorized by the Department.

(n) "Initiate a bone marrow transplantation service" means to begin operation of a bone marrow transplantation service at a site that does not provide either adult or pediatric bone marrow transplantation services and is not listed on the Department inventory as of the date an application is submitted to the Department. The term includes an adult service that is proposing to provide a pediatric bone marrow transplantation service, and a pediatric service that is proposing to provide an adult bone marrow transplantation service.

(o) "Institutional Review Board" or "IRB" means an institutional review board as defined by Public Law 93-348 which is regulated by Title 45 CFR 46.

(p) "Licensed site" means either:

(i) in the case of a single site hospital, the location of the facility authorized by license and listed on that licensee's certificate of licensure or

(ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient unit of the health facility as authorized by license and listed on that licensee's certificate of licensure.

(q) "Medicaid" means ~~the program for medical assistance administered by the Department of Community Health under the Social Welfare Act, Act No. 280 of the Public Acts of 1939, being Sections 400.1 to 400.119b of the Michigan Compiled Laws. TITLE XIX OF THE SOCIAL SECURITY ACT, CHAPTER 531, 49 STAT. 620, 1396R-6 AND 1396R-8 TO 1396V.~~

(r) "Pediatric" means, for purposes of these standards, any patient 20 years of age or less or any

patient with congenital conditions or diseases for which bone marrow transplantation is a treatment.

(s) "Planning area" means:

(i) for an adult bone marrow transplantation service, the state of Michigan.

(ii) for a pediatric bone marrow transplantation service, either:

(A) planning area one that includes the counties in health service areas 1, 2, 5, and 6, and the following counties in health service area 7: Alcona, Alpena, Cheboygan, Crawford, Montmorency, Oscoda, Otsego, and Presque Isle; or

(B) planning area two that includes the counties in health service areas 3, 4, and 8, and the following counties in health service area 7: Antrim, Benzie, Charlevoix, Emmet, Grand Traverse, Kalkaska, Leelanau, Manistee, Missaukee, and Wexford.

(t) "Qualifying project" means each application in a comparative group that has been reviewed individually and has been determined by the Department to have satisfied all of the requirements of Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws, and all other applicable requirements for approval in the Code and these standards.

(u) "Survival rate" means, for purposes of these standards, the rate calculated using the Kaplan-Meier technique and the following: (i) the date of transplantation (or, if more than one transplant is performed, the date of the first transplant) must be the starting date for calculation of the survival rate; (ii) for those dead, the date of death is used, if known. If the date of death is unknown, it must be assumed as 1 day after the date of the last ascertained survival; (iii) for those who have been ascertained as surviving within 60 days before the fiducial date (the point in time when the facility's survival rates are calculated and its experience is reported), survival is considered to be the date of the last ascertained survival, except for patients described in subsection (v); (iv) any patient who is not known to be dead, but whose survival cannot be ascertained to a date that is within 60 days before the fiducial date, must be considered as "lost to follow up" for the purposes of the survival rate calculation; (v) any patient transplanted between 61 and 120 days before the fiducial date must be considered as "lost to follow up" if he or she is not known to be dead and his or her survival has not been ascertained for at least 60 days before the fiducial date. Any patient transplanted within 60 days before the fiducial date must be considered as "lost to follow up" if he or she is not known to be dead and his or her survival has not been ascertained on the fiducial date; and (vi) the survival analyses must use the assumption that each patient in the "lost to follow up" category died 1 day after the last date of ascertained survival. However, an applicant may submit additional analyses that reflect each patient in the "lost to follow up" category as alive at the date of the last ascertained survival.

(2) The definitions of Part 222 shall apply to these standards.

Section 3. Requirements for approval for applicants proposing to initiate a bone marrow transplantation service

Sec. 3. (1) An applicant proposing to initiate a bone marrow transplantation service shall specify in the application whether the proposed service will perform either or both adult and pediatric bone marrow transplant procedures.

(2) An applicant shall specify the licensed hospital site at which the bone marrow transplantation service will be provided.

(3) An applicant proposing to initiate either an adult or pediatric bone marrow transplantation service shall demonstrate that the licensed hospital site at which the transplants will be offered provides each of the following staff, services, and programs, as of the date an application is submitted to the Department:

(a) operating rooms.

(b) continuous on-site availability, either immediate or on-call, of CT scanning, magnetic resonance imaging, ultrasound, angiography, and nuclear medicine services.

(c) dialysis.

- 159 (d) inpatient-outpatient social work.
160 (e) inpatient-outpatient psychiatry/psychology.
161 (f) clinical research.
162 (g) a microbiology and virology laboratory.
163 (h) a histocompatibility laboratory that meets the standards of the American Society for
164 Histocompatibility and Immunogenetics, or an equivalent organization, either on-site or through written
165 agreement.
166 (i) a hematopathology lab capable of performing cell phenotype analysis using flow cytometry.
167 (j) a clinical chemistry lab with the capability to monitor antibiotic and antineoplastic drug levels,
168 available either on-site or through other arrangements that assure adequate availability.
169 (k) other support services, as necessary, such as physical therapy and rehabilitation medicine.
170 (l) continuous availability of anatomic and clinical pathology and laboratory services, including
171 clinical chemistry, and immuno-suppressive drug monitoring.
172 (m) continuous availability of red cells, platelets, and other blood components.
173 (n) an active medical staff that includes, but is not limited to, the following board-certified or board-
174 eligible specialists. For an applicant that is proposing to perform pediatric transplant procedures, these
175 specialists shall be board-certified or board-eligible in the pediatric discipline of each specialty.
176 (i) anesthesiology.
177 (ii) cardiology.
178 (iii) critical care medicine.
179 (iv) gastroenterology.
180 (v) general surgery.
181 (vi) hematology.
182 (vii) infectious diseases.
183 (viii) nephrology.
184 (ix) neurology.
185 (x) oncology.
186 (xi) pathology, including blood banking experience.
187 (xii) pulmonary medicine.
188 (xiii) radiation oncology.
189 (xiv) radiology.
190 (xv) urology.
191 (o) One or more consulting physicians who are board-certified or board-eligible in each of the
192 following specialties. For an applicant proposing to perform pediatric bone marrow transplant procedures,
193 these specialists shall have specific experience in the care of pediatric patients.
194 (i) dermatology.
195 (ii) immunology.
196 (iii) neurosurgery.
197 (iv) orthopedic surgery.
198
199 (4) An applicant must provide, at the time the [Certificate of Need](#) CON application is submitted, an
200 implementation plan for the proposed bone marrow transplantation service.
201
202 (5)(a) An applicant shall demonstrate that the number of existing adult bone marrow transplantation
203 services in the planning area identified in Section 2(1)(s)(i) does not exceed three (3) adult bone marrow
204 transplantation services and that approval of the proposed application will not result in the total number of
205 adult bone marrow transplantation services exceeding three (3) in the planning area.
206 (b) An applicant shall demonstrate that the number of existing pediatric bone marrow
207 transplantation services does not exceed two (2) pediatric bone marrow transplantation services in
208 planning area one identified in Section 2(1)(s)(ii)(A) or one (1) pediatric bone marrow transplantation
209 service in planning area two identified in Section 2(1)(s)(ii)(B) and that approval of the proposed
210 application will not result in the total number of pediatric bone marrow transplantation services exceeding
211 the need for each specific pediatric planning area.

212
213 (6)(a) An applicant proposing to initiate an adult bone marrow transplantation service that will perform
214 only allogeneic transplants, or both allogeneic and autologous transplants, shall project that at least 10
215 allogeneic transplant procedures will be performed in the third 12-months of operation. An applicant
216 proposing to initiate an adult bone marrow transplantation service that will perform only autologous
217 procedures shall project that at least 10 autologous transplant procedures will be performed in the third
218 12-months of operation.

219 (b) An applicant proposing to initiate a pediatric bone marrow transplantation service that will
220 perform only allogeneic transplants, or both allogeneic and autologous transplants, shall project that at
221 least 10 allogeneic transplant procedures will be performed in the third 12-months of operation. An
222 applicant proposing to initiate a pediatric bone marrow transplantation service that will perform only
223 autologous procedures shall project that at least 10 autologous transplant procedures will be performed in
224 the third 12-months of operation.

225 (c) An applicant proposing to initiate both an adult and a pediatric bone marrow transplantation
226 service shall specify whether patients age 18-20 are included in the projection of adult procedures
227 required pursuant to subsection (a) or the projection of pediatric procedures required pursuant to
228 subsection (b). An applicant shall not include patients age 18-20 in both adult and pediatric projections
229 required pursuant to subsections (a) and (b).
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231 (7) An applicant shall provide on-site megavoltage radiation therapy services with a nominal beam
232 energy of at least 6 MEV, including the capability to perform total body irradiation.
233

234 (8) An applicant shall demonstrate, at the time an application is submitted to the Department, that
235 the licensed hospital site at which the proposed bone marrow transplantation service is proposed has an
236 institutional review board.
237

238 (9) An applicant proposing to initiate a pediatric bone marrow transplantation service shall
239 demonstrate that the licensed hospital site at which the pediatric transplant procedures will be performed
240 has each of the following, at the time an application is submitted to the Department:

- 241 (a) a designated pediatric inpatient oncology unit.
 - 242 (b) a pediatric inpatient intensive care unit.
 - 243 (c) membership status in either the Pediatric Oncology Group (POG) or the Children' s Cancer
244 Group (CCG).
 - 245 (d) a pediatric tumor board that meets on a regularly scheduled basis.
 - 246 (e) family support group services, provided either directly or through written agreements.
 - 247 (f) a pediatric cancer program with the following staff:
 - 248 (i) a director who is either a board-certified immunologist who has specific training and experience
249 in bone marrow transplantation or a board-certified pediatric hematologist/oncologist.
 - 250 (ii) nurses with training and experience in pediatric oncology.
 - 251 (iii) social workers with training and experience in pediatric oncology.
 - 252 (iv) pediatric psychologists.
 - 253 (v) child life specialists.
- 254

255 (10)(a) An applicant proposing to initiate either a new adult or pediatric bone marrow transplantation
256 service shall submit, in its application, a written consulting agreement with an existing bone marrow
257 transplantation service that meets each of the requirements in subsection (b).

258 (b) The written consulting agreement required by subsection (a) shall specify the term of the
259 agreement and the roles and responsibilities of both the existing and proposed service, including at least
260 the following:

261 (i) The term of the written consulting agreement is no less than 36 months after the proposed
262 service begins to perform bone marrow transplant procedures.

263 (ii) One or more representatives of the existing bone marrow transplantation service have been
264 designated as staff responsible for carrying out the roles and responsibilities of the existing service.
265

- (iii) The existing service shall evaluate and make recommendations to the proposed service on policies and procedures, including time tables, for at least each of the following:
- (A) nursing services.
 - (B) infection control.
 - (C) nutritional support.
 - (D) staff needs and training.
 - (E) inpatient and outpatient medical coverage.
 - (F) transfusion and blood bank policies.
 - (G) transplant treatment protocols.
 - (H) hematopoiesis laboratory services and personnel.
 - (I) data management.
 - (J) quality assurance program.
- (iv) Specify a schedule of site visits by staff of the existing bone marrow transplantation service that, at a minimum, includes:
- (A) 6 visits during the first 12-months of operation of the proposed service.
 - (B) 4 visits during each the second 12-months and third 12-months of operation of the proposed service.
- (v) Specify that the purpose of the site visits required by subdivision (iv) is to assess the proposed service and make recommendations related to quality assurance mechanisms of the proposed service, including at least each of the following:
- (A) a review of the number of patients transplanted.
 - (B) transplant outcomes.
 - (C) all infections requiring treatment or life-threatening toxicity, defined for purposes of this agreement as National Cancer Institutes grade #3 or greater toxicity, excluding hematological toxicity.
 - (D) all deaths occurring within 100 days from transplant.
 - (E) each of the requirements of subdivision (iii).
- (vi) Specify that a written report and minutes of each site visit shall be completed by the existing bone marrow transplantation service and sent to the proposed service within 2 weeks of each visit, and that copies of the reports and minutes shall be available to the Department upon request. At a minimum, the written report shall address each of the items in subdivision (v).
- (vii) Specify that the existing bone marrow transplantation service shall notify the Department and the proposed service immediately if it determines that the proposed service may not be in compliance with any applicable quality assurance requirements, and develop jointly with the proposed service a plan for immediate remedial actions.
- (viii) Specify that the existing bone marrow transplantation service shall notify the Department immediately if the consulting agreement required pursuant to these standards is terminated and that the notification shall include a statement describing the reasons for the termination.
- (c) For purposes of subsection (10), "existing bone marrow transplantation service" means a service that meets all of the following:
- (i) currently is and has been performing, for at least 3 years, the types of transplants (allogeneic or autologous; adult or pediatric) proposed to be performed by the applicant.
 - (ii) performed at least 15 pediatric allogeneic transplants or 40 adult allogeneic transplants in the most recent 12-month period prior to the date an application is submitted to the Department.
 - (iii) currently is certified by the National Marrow Donor Program and is located in the United States.
- (d) An applicant shall document that the existing bone marrow transplantation service meets the requirements of subsection (c).

Section 4. Additional requirements for applications included in comparative reviews

Sec. 4. (1) Any application subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or these standards, shall be grouped and reviewed with other applications in accordance with the ~~Certificate of Need~~ CON rules applicable to comparative reviews.

(2)(a) A qualifying project will have points awarded based on the number of bone marrow transplantation services, adult or pediatric, as applicable, listed on the Department inventory in the health service area in which the proposed service will be located, on the date the application is submitted to the Department, as shown in the following schedule:

| Number of BMT Transplant Services (adult or pediatric, as applicable) in HSA | Points Awarded |
|---|-------------------|
| Two or more services | 0 |
| One service | 2 |
| No services | 4 |

(b) A qualifying project will have up to 4 points awarded based on the percentage of the medical/surgical indigent volume at the licensed hospital site at which the proposed bone marrow transplantation service will be provided in accordance with the following:

(i) For each applicant in the same comparative group, determine the medical/surgical indigent volume, rounded to the nearest whole number, for each licensed hospital site at which a bone marrow transplantation service is proposed to be provided. Determine the licensed hospital site that has the highest indigent volume in the same comparative group. Divide the medical/surgical indigent volume for that licensed hospital site by 4.0. The result is the indigent volume factor.

(ii) For each applicant in the same comparative group, divide the medical/surgical indigent volume by the indigent volume factor determined in subdivision (i). The result, to the first decimal place, is the number of points that will **BE** awarded to each applicant pursuant to this subsection.

For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its total charges expressed as a percentage as determined by the Michigan Department of Community Health Medical Services Administration pursuant to Chapter VIII of the Medical Assistance Program Hospital Manual. The indigent volume data being used for rates in effect at the time the application is deemed submitted will be used by the Department in determining the number of points awarded to each qualifying project.

(c) A qualifying project will have 2 points awarded if an applicant documents that, during the 36-month period prior to the date an application is submitted to the Department, at least 15 patients received pre- and post-transplant care at the licensed hospital site at which the bone marrow transplant procedures will be performed and were referred for and received a bone marrow transplant at an existing bone marrow transplantation service, and submits documentation from the existing bone marrow transplantation service(s) of these referrals.

(3) Each application in a comparative review group shall be individually reviewed to determine whether the application has satisfied all the requirements of Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws, and all other applicable requirements for approval in the Code and these standards. If the Department determines that one or more of the competing applications satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1) being Section 333.22225(1) of the Michigan Compiled Laws, and which have the highest number of points when the results of subsection (2) are totaled. If two or more qualifying projects are determined to have an identical number of points, the Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws, in the order in which the applications were received by the Department, based on the date and time stamp placed on the application for [Certificate of Need](#) form (form T-150-G-1.01 or any subsequent replacement form) by the Health

Facilities Section(or the administrative unit of the Department responsible for administering the [Certificate of NeedCON](#) program) when an application is submitted.

(4) No points will be awarded to an applicant under specific subsections of Section 4 if information presented in Section 4 is inconsistent with related information provided in other portions of the [Certificate of NeedCON](#) application.

Section 5. Requirements for approval -- all applicants

Sec. 5. AN APPLICANT SHALL PROVIDE VERIFICATION OF MEDICAID PARTICIPATION AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT. IF THE REQUIRED DOCUMENTATION IS NOT SUBMITTED WITH THE APPLICATION ON THE DESIGNATED APPLICATION DATE, THE APPLICATION WILL BE DEEMED FILED ON THE FIRST APPLICABLE DESIGNATED APPLICATION DATE AFTER ALL REQUIRED DOCUMENTATION IS RECEIVED BY THE DEPARTMENT.

Section 56. Project delivery requirements -- terms of approval for all applicants

Sec. 56. (1) An applicant shall agree that, if approved, the bone marrow transplantation service shall be delivered in compliance with the following terms of [Certificate of NeedCON](#) approval:

(a) Compliance with these standards. An applicant shall immediately report to the Department any changes in key staff or other aspects of the bone marrow transplantation service that may affect its ability to comply with these standards.

(b) Compliance with applicable safety and operating standards.

(c) Compliance with the following quality assurance standards, as applicable, no later than the date the first bone marrow transplant procedure, allogeneic or autologous, is performed:

(i) An applicant shall establish and maintain, either on-site or through written agreements, all of the following:

(A) 24-hour blood bank support, including pheresis capability, irradiated blood, products suitable for cytomegalovirus-negative transplants, and blood component therapy.

(B) a cytogenetics and/or molecular genetic laboratory.

(C) a processing and cryopreservation laboratory that meets the standards of the Foundation for Accreditation of Hematopoietic Cell Therapy (FAHCT) or an equivalent organization.

(D) for a program that performs allogeneic transplants, a histocompatibility laboratory that has the capability of DNA-based HLA-typing and meets the standards of the American Society for Histocompatibility and Immunogenetics or an equivalent organization.

(E) anatomic and clinical pathology with competency in interpreting pathologic findings related to graft-v-host disease (programs performing allogeneic transplants) and other opportunistic infections in immuno-compromised hosts (programs performing allogeneic or autologous transplants).

(F) therapeutic drug monitoring.

(ii) An applicant shall establish and maintain, at the licensed hospital site at which the transplants are performed, both of the following:

(A) a protective environmental bone marrow transplant inpatient unit for immuno-suppressed patients that has an isolation policy, an infection control plan specific to that unit, and an air handling system capable of preventing nosocomial infections disseminated from central heating and cooling systems and ambient air.

(B) a specialized intensive care unit capable of treating immuno-suppressed neutropenic patients.

(iii) An applicant shall establish and maintain written policies related to outpatient care for bone marrow transplantation patients, including at least the following:

(A) the ability to evaluate and provide treatment on a 24-hour basis.

(B) nurses experienced in the care of bone marrow transplantation patients.

(C) a designated outpatient area for patients requiring long-duration infusions or the administration of multiple medications or blood product transfusions.

424 (iv) A bone marrow transplantation service shall establish and maintain a dedicated transplant team
425 that includes at least the following staff:

426 (A) a transplant team leader, who is a physician that is board-certified in at least one of the following
427 specialties: hematology, medical oncology, immunology, or pediatric hematology/oncology, as appropriate,
428 and has had either at least one year of specific clinical training or two years of experience, both inpatient
429 and outpatient, as an attending physician principally responsible for the clinical management of patients
430 treated with hematopoietic transplantation. If the bone marrow transplantation service performs allogeneic
431 transplants, the team leader's experience shall include the clinical management of patients receiving an
432 allogeneic transplant. The responsibilities of the transplant team leader shall include overseeing the
433 medical care provided by attending physicians, reporting required data to the Department, and
434 responsibility for ensuring compliance with the all applicable project delivery requirements.

435 (B) one or more attending physicians with specialized training in pediatric and/or adult, as
436 appropriate, bone marrow transplantation. If a service performs allogeneic transplants, at least one
437 attending physician shall have specialized training in allogeneic transplantation, adult or pediatric, as
438 appropriate. An attending physician shall be board-certified or board-eligible in hematology, medical
439 oncology, immunology, or pediatric hematology/oncology, as appropriate.

440 (C) on-site availability of board-certified or board-eligible consulting physicians, adult and/or pediatric,
441 as appropriate, in at least the following specialties: anatomic pathology with competence in graft versus host
442 disease (services performing allogeneic transplants) and other opportunistic diseases (services performing
443 allogeneic or autologous transplants), cardiology, gastroenterology, infectious diseases with experience in
444 immuno-compromised hosts, nephrology, psychiatry, pulmonary medicine, and radiation oncology with
445 experience in total body irradiation, and an intensivist who is board-certified in critical care.

446 (D) a transplant team coordinator, who shall be responsible for providing pre-transplant patient
447 evaluation and coordinating treatment and post-transplant follow-up and care.

448 (E) a nurse to patient ratio necessary to provide care consistent with the severity of a patient's clinical
449 status.

450 (F) nurses with specialized training in pediatric and/or adult, as appropriate, bone marrow
451 transplantation, hematology/oncology patient care, administration of cytotoxic therapies, management of
452 infectious complications associated with compromised host-defense mechanisms, administration of blood
453 components, the hemodynamic support of the transplant patient, and managing immuno-suppressed
454 patients.

455 (G) a pharmacist experienced with the use of cytotoxic therapies, use of blood components, the
456 hemodynamic support of the transplant patient, and the management of immuno-suppressed patients.

457 (H) dietary staff capable of providing dietary consultations regarding a patient's nutritional status,
458 including total parenteral nutrition.

459 (I) designated social services staff.

460 (J) designated physical therapy staff.

461 (K) data management personnel designated to the bone marrow transplantation service.

462 (L) for an applicant performing pediatric bone marrow transplants, a child-life specialist.

463 (v) In addition to the dedicated transplant team required in subdivision (iv), an applicant's staff shall
464 include a patient ombudsman, who is familiar with the bone marrow transplantation service, but who is not a
465 member of the transplant team.

466 (vi) An applicant shall develop and maintain patient management plans and protocols that include the
467 following:

468 (A) therapeutic and evaluative procedures for the acute and long-term management of a patient.

469 (B) patient management and evaluation during the waiting, in-hospital and immediate post-
470 discharge phases of the service.

471 (C) long-term management and evaluation, including education of the patient, liaison with the
472 patient's attending physician, and the maintenance of active patient records for at least 5 years.

473 (D) IRB approval of all clinical research protocols, or if transplantation does not require an IRB-
474 approved clinical research protocol, written policies and procedures that include at least the following:
475 donor, if applicable, and recipient selection, transplantation evaluations, administration of the preparative
476 regimen, post-transplantation care, prevention and treatment of graft-versus-host disease (allogeneic

transplants), and follow-up care.

(vii) An applicant shall establish and maintain a written quality assurance plan.

(viii) An applicant shall implement a program of education and training for nurses, technicians, service personnel, and other hospital staff.

(ix) An applicant shall participate actively in the education of the general public and the medical community with regard to bone marrow transplantation, and make donation literature available in public areas of the institution.

(x) An applicant shall establish and maintain an active, formal multi-disciplinary research program related to the proposed bone marrow transplantation service.

(xi) An applicant shall operate, either on-site or under its direct control, a multi-disciplinary selection committee which includes, but is not limited to, a social worker, a mental health professional, and physicians experienced in treating bone marrow transplant patients.

(xii) A pediatric bone marrow transplant service shall maintain membership status in either the Pediatric Oncology Group (POG) or the Children's Cancer Group (CCG). If an applicant organization discontinues membership in either the POG or the CCG, an applicant shall obtain membership in the alternate organization within six months of discontinuing its membership.

(xiii) For purposes of evaluating subsection (c), except subdivision (xii), the Department shall consider it *prima facie* evidence as to compliance with the applicable requirements if an applicant documents that the bone marrow transplantation service is accredited by the National Marrow Donor Program (NMDP) or the Foundation for the Accreditation of Hematopoietic Cell Therapy (FAHCT).

(XIV) AN APPLICANT SHALL PARTICIPATE IN MEDICAID AT LEAST 12 CONSECUTIVE MONTHS WITHIN THE FIRST TWO YEARS OF OPERATION AND CONTINUE TO PARTICIPATE ANNUALLY THEREAFTER.

(d) Compliance with the following terms of approval:

(i) An applicant shall perform the applicable required volumes as follow:

(A) An adult bone marrow transplantation service that performs only allogeneic transplants, or both allogeneic and autologous transplants, shall perform at least 10 allogeneic transplants in the third 12-months of operation. If an adult service performs only autologous transplants, the service shall perform at least 10 autologous transplants in the third 12-months of operation. After the third 12-months of operation, an applicant shall perform at least 30 adult transplants in any 36-month consecutive period, with no fewer than 5 allogeneic in any 12-month period, beginning with the third 12-months of operation, and thereafter.

(B) A pediatric bone marrow transplantation service that performs only allogeneic transplants, or both allogeneic and autologous transplants, shall perform at least 10 allogeneic transplants in the third 12-months of operation. If a pediatric service performs only autologous transplants, the service shall perform at least 10 autologous transplants in the third 12-months of operation. After the third 12-months of operation, an applicant shall perform at least 30 pediatric transplants in any 36-month consecutive period, with no fewer than 5 allogeneic transplants in any 12-month period, beginning with the third 12-months of operation, and thereafter.

(C) A bone marrow transplantation service that performs both adult and pediatric bone marrow transplants shall specify whether each patient age 18-20 is included in the category of adult procedures or the category of pediatric procedures. An applicant shall determine for each patient age 18-20 whether to record that patient as an adult or a pediatric procedure, but an applicant shall record each patient age 18-20 in only 1 category.

(ii) The applicant shall participate in a data collection network established and administered by the Department ~~OR ITS DESIGNEE~~. The data may include, but is not limited to, annual budget and cost information, demographic and diagnostic information, primary and secondary diagnoses, whether the transplant procedure was a first or repeat transplant procedure, length of stay, the volume of care provided to patients from all payor sources, and other data requested by the Department and approved by the ~~Certificate of Need~~ CON Commission. The applicant shall provide the required data on an individual basis for each designated licensed site; in a format established by the Department; and in a mutually-agreed upon media. The Department may elect to verify the data through on-site review of appropriate records. In addition, an applicant shall report at least the following data for each patient:

- (A) disease type.
- (B) transplant type, i.e., related allogeneic, unrelated allogeneic, and autologous.
- (C) source of hematopoietic stem cell, i.e., bone marrow, peripheral circulation, cord blood, etc.
- (D) patient age, i.e., adult or pediatric as defined by these standards.
- (E) data on 100-day, 6-month, 1-year, 2-year, and 5-year survival rates.
- (F) relapse rates at 6-months, 1-year, and 5-years post-transplant.
- (G) median follow-up, and patients lost-to-followup.
- (H) cause(s) of death, if applicable.
- (I) additional summary information, as applicable.

An applicant annually shall report for its bone marrow transplantation service annual and cumulative survival rates by type of transplant performed reported in actual number of transplants by disease category, transplant type, i.e., related allogeneic, unrelated allogeneic, and autologous; source of hematopoietic stem cell; patient age, i.e., adult or pediatric, as defined by these standards; and relapse rates at 100-days, 6-months, one year, and five years post-transplant. For purposes of these standards, procedure-related mortality is defined as death occurring within 100 days from bone marrow transplant.

(iii) The applicant shall maintain an organized institutional transplant registry for recording ongoing information on its patients being evaluated for transplant and on its transplant recipients and shall participate in the national and international registries applicable to the bone marrow transplantation service.

(iv) An applicant, to assure that the bone marrow transplantation service(s) will be utilized by all segments of the Michigan population, shall:

- (A) not deny the services to any individual based on ability to pay or source of payment;
- (B) provide the services to all individuals in accordance with the patient selection criteria developed by appropriate medical professionals, and approved by the Department; and
- (C) maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(v) ~~An~~ THE applicant shall provide the Department with a notice stating the date on which the first transplant procedure is performed and such notice shall be submitted to the Department ~~within 10 days after the first transplant procedure is performed~~ CONSISTENT WITH APPLICABLE STATUTE AND PROMULGATED RULES. An applicant that initially does not perform both allogeneic and autologous procedures also shall notify the Department when it begins to perform either allogeneic or autologous procedures, whichever was not performed initially by the applicant.

(vi) An applicant shall notify the Department immediately if the consulting agreement required pursuant to Section 3(10) of these standards is terminated prior to the end of the first 36-months of operation of the bone marrow transplantation service. The notification shall include a statement describing the reasons for the termination. An applicant shall have 30 days following termination of that agreement to enter into a written consulting agreement that meets the requirements of Section 3(10). An applicant shall provide the Department with a copy of that written consulting agreement.

(vii) The Department may use the information provided pursuant to Section 3(10) of these standards in evaluating compliance with the requirements of this section.

(2) The agreements and assurances required by this section, as applicable, shall be in the form of a certification authorized by the governing body of the applicant or its authorized agent.

Section 67. Documentation of projections

Sec. 67. An applicant required to project volumes of service under Section 3 shall specify how the volume projections were developed. This specification of projections shall include a description of the data source(s) used, assessments of the accuracy of these data, and the statistical method used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.

Section 78. Health Service Areas

Sec. 78. Counties assigned to each health service area are as follows:

| HSA | COUNTIES | | |
|-----|---|--|---|
| 1 | Livingston Macomb Wayne | Monroe Oakland | St. Clair Washtenaw |
| 2 | Clinton Eaton | Hillsdale Ingham | Jackson Lenawee |
| 3 | Barry Berrien Branch | Calhoun Cass Kalamazoo | St. Joseph Van Buren |
| 4 | Allegan Ionia Kent Lake | Mason Mecosta Montcalm Muskegon | Newaygo Oceana Osceola Ottawa |
| 5 | Genesee | Lapeer | Shiawassee |
| 6 | Arenac Bay Clare Gladwin Gratiot | Huron Iosco Isabella Midland Ogemaw | Roscommon Saginaw Sanilac Tuscola |
| 7 | Alcona Alpena Antrim Benzie Charlevoix Cheboygan | Crawford Emmet Gd Traverse Kalkaska Leelanau Manistee | Missaukee Montmorency Oscoda Otsego Presque Isle Wexford |
| 8 | Alger Baraga Chippewa Delta Dickinson | Gogebic Houghton Iron Keweenaw Luce | Mackinac Marquette Menominee Ontonagon Schoolcraft |

Section 89. Department Inventory of Bone Marrow Transplantation Services

Sec 89. Appendix A sets forth the bone marrow transplantation services included in the Department inventory of bone marrow transplantation as of the effective date of these standards. Modifications to Appendix A shall be made by the Department based on decisions made on [Certificate of Need](#) CON applications and Certificates of Need.

632 **Section 910. Effect on prior ~~Certificate of Need~~CON Review Standards; comparative reviews**

633
634 Sec. 910. (1) These ~~Certificate of Need~~CON review standards supersede and replace the ~~Certificate~~
635 ~~of Need~~CON Review Standards for Extrarenal Transplantation Services pertaining to bone marrow
636 transplantation services approved by the ~~Certificate of Need~~CON Commission ~~ON JUNE 4, 1997~~ and
637 effective on ~~December 18, 1993~~JULY 26, 1997.

638
639 (2) Projects reviewed under these standards shall be subject to comparative review.
640

DEPARTMENT INVENTORY OF BONE MARROW TRANSPLANTATION SERVICES*

ADULT

Detroit Medical Center (Harper Hospital)--Detroit/Wayne
Henry Ford Hospital--Detroit/Wayne
Oakwood Hospital--Dearborn/Wayne
University of Michigan--Ann Arbor/Washtenaw

Autologous Only

Mark G. Campbell, M.D.--710 Kenmoor, S.E., Grand Rapids/Kent
Richard K. Rotman, D.O.--710 Kenmoor, S.E., Grand Rapids/Kent
Michael H. Zakem, D.O.--710 Kenmoor, S.E., Grand Rapids/Kent
David Oviatt, M.D.--245 State Street, Suite 105, Grand Rapids/Kent

PEDIATRIC

Planning Area One

Detroit Medical Center (Children' s Hospital **HARPER**)--Detroit/Wayne
University of Michigan--Ann Arbor/Washtenaw

Planning Area Two

Butterworth Hospital--Grand Rapids/Kent

*Inventory updated 10/29/97. Applicant must contact the Department for current inventory. Note the services listed do not reflect any applications under appeal or pending a final Department decision.